DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems, LLC
% Ms. Robin Martin
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA WI 53188

November 24, 2014

Re: K142098
Trade/Device Name: SIGNA PET/MR
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO
Dated: November 14, 2014
Received: November 17, 2014

Dear Ms. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k142098

Device Name
SIGNA PET/MR

Indications for Use *(Describe)*

The SIGNA PET/MR system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and isocentrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and / or PET imaging. These systems are intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders. MR is intended to produce transverse, sagittal, coronal and oblique cross-sectional MR images, spectroscopic images and/ or spectra, and displays the internal structure and/or function of the human body. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, approved contrast agents may be used, as described in their labeling. This system may also be used for imaging during interventional procedures when performed with MR compatible devices, such as MR safe biopsy needles. PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer.

The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	July 31, 2014
Submitter (Manufacturer):	GE Medical Systems, LLC. 3200 N. Grandview Blvd. Waukesha, WI 53188
Manufacturing Site:	GE Medical Systems, LLC. 3000 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact Person:	Robin Martin Regulatory Affairs Manager GE Medical Systems, LLC Phone: (414) 336-9228 Fax: (262) 894-4968
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Medical Systems, LLC Phone: (262) 521-6848 Fax: (262) 894-4968
Device Trade Name:	SIGNA PET/MR
Common/Usual Name:	Magnetic Resonance Diagnostic Device / Positron Emission Tomography (PET) System
Classification Names: Product Code:	Emission Computed Tomography System per 21 CFR 892.1200 OUO
Predicate Device(s):	K133226 Siemens Biograph mMR Reference Devices: K081496 Discovery XR (Currently marketed as Discovery PET/CT 690) K132376 Discovery MR750w 3.0T
Device Description:	The GE SIGNA PET/MR system is a combined Magnetic Resonance Diagnostic Device (MRDD) and Positron Emission Tomography (PET) scanner. The system is designed for whole body oncology, neurology and cardiology examinations. The SIGNA PET/MR system provides simultaneous acquisition of high-resolution metabolic and anatomic information from the two major components of each system (MR and PET). Additional components of the system include: a patient table and both the acquisition and processing workstations with associated software. The SIGNA PET/MR includes a 3.0T superconducting magnet, gradient coil, body coil and local surface RF coils based on those of the reference device Discovery MR750w 3.0T. The system includes dual drive capabilities. The SIGNA PET detectors have been modified from those of the reference device, the Discovery PET/CT 690, to allow them to be integrated into the bore of the MR. This allows for simultaneous, precisely aligned whole body MR and PET acquisition. Similar to Discovery PET/CT D690, PET supports Time of Flight

	(ToF). SIGNA PET/MR software is based on a combination of Discovery MR750w with Discovery PET/CT 690 software. It is used for patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements. The SIGNA PET/MR system and surface coil suite, the subject of this application, is substantially equivalent to the commercially available devices above with modifications made to integrate the two modalities together into a whole-body system.
Intended Use:	The SIGNA PET/MR system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and isocentrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and / or PET imaging. These systems are intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders. The MR is intended to produce transverse, sagittal, coronal and oblique cross-sectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human body. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, approved contrast agents may be used, as described in their labeling. This system may also be used for imaging during interventional procedures when performed with MR compatible devices, such as MR safe biopsy needles. The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.
Technology:	The proposed SIGNA PET/MR employs much of the same fundamental scientific technology as its respective reference devices for MR and PET technology and has the same intended use as the claimed predicate device. The proposed device combines PET and MR technologies for simultaneous imaging. Subsequently, the PET subsystem requires different technology from the Discovery PET/CT 690 for compatibility with the MR subsystem (detectors, chiller system, etc.). Additionally, MR images are used to correct for PET attenuation compared to the reference PET/CT, which uses CT technology for PET attenuation.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The SIGNA PET/MR and Coil Suite comply with the following voluntary

	standards (3rd Edition): • IEC 60601-1 (system and coil suite) • IEC 60601-1-2 (system and coil suite) • IEC 60601-2-33 (system and coil suite) In addition, this SIGNA PET/MR scanner and surface coils are in compliance with the applicable NEMA standards, including NEMA MS1, MS2, MS3, MS4, MS5, MS8, MS9, NEMA NU2 and NEMA PS3.1- 3.18. The following quality assurance measures were applied to the development of the system: • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) <u>Summary of Clinical Tests:</u> Sample images from the SIGNA PET/MR were collected from multiple sites to confirm simultaneous diagnostic image quality.
Conclusion:	GE Medical Systems, LLC. considers the SIGNA PET/MR to be as safe, as effective, and performance is substantially equivalent to the predicate device and reference devices.